

**REMARKS**

Claims 20-30 and 33-44 are currently pending.

Claims 20 has been amended to incorporate the features of Claims 31 and 32 which have been cancelled herein. Claims 34, 39 and 40 have also been amended to recite the feature that the first and second fill openings extend from the common side edge of the respective first and second film envelopes to the respective first interior volume and second interior volume. Support for these amendments can be found, for example, in the specification on page 11, lines 9-12, and in the Claims as originally filed. No new matter has been introduced by these amendments.

**I. Request for Reconsideration of the Constructive Restriction**

The Office states that previously submitted claims 34-44 are directed to an invention that is independent or distinct from the invention originally claimed and therefore alleges that Applicants have constructively elected the invention recited in Claims 20-33. At least for the reasons set forth below, Applicants respectfully traverse the Office's withdraw of Claim 34-44 and further request reconsideration of the instant restriction.

Specifically, the Office contends that the addition of features directed to a "non-crosslinking self-shaping dispersion" and "passing a non-crosslinking self-shaping dispersion through the first fill opening by vacuum pumping" gives rise to inventions that are independent or distinct from the invention originally claimed. However, to be a valid restriction, the Office must establish that (1) the "inventions" are either independent or distinct, and (2) that examination of more than one of the "inventions" would constitute a burden to the Examiner. Applicants note that the constructive restriction/election at least fails to provide sufficient basis to indicate that examination of more than one of the "inventions" would overly burden the Examiner. A non-crosslinking self-shaping dispersion is a species of the generic self-shaping dispersion recited in Applicants Claim 20. Likewise, vacuum pumping is a species of the generic passing of a self-shaping

dispersion through the first fill opening as also recited in Applicants' Claim 20. Thus the examination of Applicants' Claim 20 requires a search of the same art as an examination of Applicants' Claims 34, 39 and 40. Accordingly, the second requirement for a proper restriction has not been met. Applicants thus respectfully request reconsideration of the constructive election.

## **II. Rejections under 35 U.S.C. § 102(b)**

The Office Action has rejected Claims 20 and 25-27 under 35 U.S.C. § 102(b) as allegedly being anticipated by the disclosure of Canadian Patent Application No. 2,204,490 (hereinafter "Wild"). To this end, it is well established that a proper novelty defeating reference must disclose each and every feature of the rejected Claim. As set forth below, Wild fails to disclose each and every feature of Applicants' Claim 20 and, as such, the instant rejection of Claims 20 and 25-27 must be withdrawn.

Initially, Applicants draw attention to the Office's express admission on page 4 of the instant Office Action wherein it states that Wild fails to specifically set forth manufacturing steps for producing a two-layered breast prosthesis. Thus, the Office has admitted that Wild does not anticipate each and every feature of Applicants Claim 20. For this reason alone, the instant rejection under section 102(b) is in error and must be withdrawn.

However, as amended herein, Claim 20 further recites the feature that the respective first and second fill openings extend from the common side edge to the respective first and second interior volumes. In contrast, Wild only discloses a fill opening that consists of an access hole in the rear film wall of the prosthesis. *See*, Figures 3 and 4. The fill opening depicted in Wild's Figures 3 and 4 does not extend from the common side edge to the respective first and second interior volumes.

Accordingly, for at least these reasons, Wild fails to disclose each and every feature of Applicants' Claims. Therefore, it is respectfully submitted that the Office has

failed to present a proper novelty rejection and, as such, the instant rejection of Claims 20 and 25-27 must be withdrawn.

### III. Rejections under 35 U.S.C. § 103(a)

The Office Action has rejected Claims 20-33 as allegedly being obvious and unpatentable under 35 U.S.C. § 103(a) based on a number of grounds. To that end, it is well established that a *prima facie* case of obviousness requires that the art of record must teach or suggest the invention as a whole and there must be the requisite motivation for the alleged modification or combination proposed in the Office Action. As set forth in detail below, the alleged rejections of Claims 20-33 fail to satisfy these requirements and, as such, these rejections must be withdrawn.

#### A. **Canadian Pat. App. No. 2,204,490 in view of U.S. Patent No. 5,902,335**

The Office has rejected Claims 20-27 as allegedly being obvious and unpatentable over the disclosure of Canadian Patent No. 2,204,490 (hereinafter "Wild") in view of U.S. Patent No. 5,902,335 (hereinafter "Snyder").

As amended, the process of Applicants' Claim 20 recites, in part, providing: (i) a first film envelope configured to define a first interior volume; and (ii) a second film envelope joined to the first film envelope along a common side edge to thereby define a second interior volume, wherein said second film envelope and said first film envelope share a common interstitial film wall and wherein said first and said second film envelopes further comprise a respective first and a second fill opening extending from the common side edge to the respective first interior volume and second interior volume. Further, amended Claim 20 also recites, in part, a process step comprising passing a self-shaping dispersion through the first fill opening, wherein air is removed from the self-shaping dispersion prior to passing the dispersion through the first fill opening.

Initially, the Office recognizes and admits that Wild fails to teach or suggest the specific process steps recited in Applicants' claims. However, notwithstanding this recognized deficiency, the Office then makes the unsupported allegation that it

nonetheless would have been obvious to one of skill in the art to arrive at the process of Applicants' Claims in view of the combined teaching of Wild, further in view of Snyder. To that end, the combined teachings of Wild in view of Snyder still fail to teach or suggest the Applicants' process as whole.

Neither Wild nor Snyder expressly disclose providing a first and second fill opening extending from the common side edge of a joined first and second film envelop to the respective first interior volume and second interior volume. As discussed in detail above, Wild only discloses a prosthesis having a fill opening positioned in the back wall of the prosthesis and thus necessarily fails to disclose a first and second fill valve extending from a common side edge of a joined first and second film envelope.

With respect to Snyder, Applicants initially note that the disclosure is directed to a breast prosthesis having two cured layers and does not disclose a prosthesis having any uncured layers. To that end, the relevant method of Snyder recites filling pre-formed bags through an access hole provided to each bag. As one of skill in the art will appreciate, an access hole as disclosed in Snyder is not an opening that extends from a common side edge of adjoining film bags. More specifically, Snyder states that the access holes are provide to each bag after the welded formation of the adjoining bags. *See*, Col. 4, lines 60-64. Simply put, access holes that are provided after the welded formation of a first and second bag having a common side edge cannot extend from the common side edge of the welded formation.

Moreover, neither Wild nor Snyder teach or even suggest a self shaping dispersion that has had air removed therefrom. Therefore, for at least these reasons, even assuming arguendo that one of skill in the art would seek to combine these disclosures (which he would not) it is evident that the resulting combination fails to provide the process of Applicants' Claim 20 as a whole.

Notwithstanding the fact that the alleged combination of Wild in view of Snyder fails to provide the process of Applicants' Claims 20-27, also notably absent from this

alleged combination is the precise identification of a suggestion, teaching or motivation in these prior art references that would lead one of ordinary skill in the art to make the alleged combination. It is not enough to combine references without some objective reason to do so. To combine prior art references without evidence of such suggestion, teaching or motivation is an impermissible hindsight reconstruction and simply takes the inventor's disclosure as a blueprint for piecing together the prior art in an effort to defeat patentability. *See In re Dembiczak*, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999). Simply put, the motivation to combine references can not come from the invention itself. *See In re Oetiker*, 977 F.2d 1443, 1447, 24 USPQ2d 1443, 1446 (Fed. Cir. 1992).

The Office points to nothing in Wild that suggests his breast prosthesis could be manufactured in any manner other than the method disclosed therein. Similarly, the Office points to nothing in Snyder that suggests his method for producing a breast prosthesis having two cured layers could be used to manufacture a prosthesis having an uncured self-shaping dispersion layer. Accordingly, in the absence of such precise identification of a suggestion, teaching or motivation in these prior art references, the Office has necessarily presented a rejection based solely on improper hindsight reconstruction.

Accordingly, it is respectfully submitted that the Office has failed to present a *prima facie* case of obviousness and, as such, the current rejection of Claims 20-27 must be withdrawn.

**B. U.S. Patent Number 4,380,569**

The Office has further rejected Claim 28 as allegedly being obvious and unpatentable over the disclosures of Wild and Snyder further in view of U.S. Patent Number 4,380,569 (hereinafter "Shaw").

Initially, it is axiomatic that "dependent claims are non-obvious under section 103 if the independent claims from which they depend are non-obvious." *See In re Fine*, 5

U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988). Claim 20, the independent claim from which Claim 28 depends, is non-obvious and in condition for allowance as set forth in detail above. Thus, for at least this reason alone, the instant rejection of Claim 28 must also be withdrawn. However, notwithstanding the fact that the combined teachings of Wild in view of Snyder fails obviate the invention recited in Claim 20, the Office's further reliance on the disclosure of Shaw is similarly misplaced.

Specifically, the Office contends that it would have been obvious for the skilled artisan to seek guidance from Shaw's disclosure of microspheres having certain physical parameters. Shaw only discloses the use of microspheres in the production of cured gel forms, whereas, the microspheres of Applicants' claim 28 are disposed within an uncured self-shaping dispersion layer. Shaw fails to disclose or even suggest the use of microspheres in an uncured self-shaping dispersion layer and, as such, lacks the requisite motivation to make the alleged combination proposed by the Office. Simply put, one of skill in the art would not have been motivated to look to the disclosure of Shaw for guidance in the use of microspheres in an uncured self shaping dispersion layer.

Accordingly, for at least these reasons, it is respectfully submitted that the Office has failed to present a *prima facie* case of obviousness and, as such, the current rejection of Claim 28 must be withdrawn.

**C. U.S. Patent Number 5,738,812**

The Office has also rejected Claims 29 and 30 as allegedly being obvious and unpatentable over the disclosures of Wild and Snyder further in view of U.S. Patent Number 5,738,812 (hereinafter "the '812 patent").

Initially, as stated above, "dependent claims are non-obvious under section 103 if the independent claims from which they depend are non-obvious." Once again, Claim 20, the independent claim from which Claims 29 and 30 also depend, is non-obvious and in condition for allowance as set forth in detail above. Thus, for at least this reason alone,

the instant rejection of Claims 29 and 30 must also be withdrawn. However, not withstanding the fact that the combined teachings of Wild in view of Snyder fail to obviate the invention recited in Claim 20, the Office's further reliance on the disclosure of the '812 patent is similarly misplaced.

The Office contends that it would have been obvious for the skilled artisan to seek guidance from the '812 patent's teaching of a silicone gel and microsphere mixture having certain viscosities. However, the silicone and microsphere mixture disclosed in the '812 patent and relied upon by the Office is a curable silicone gel mixture that is cured to provide a vulcanized rubber mass having a reduced density, whereas, the silicone and microsphere mixture of Applicants' Claims 29 and 30 is disposed within a self-shaping dispersion layer that remains uncured. The '812 patent fails to disclose a prosthesis having any uncured self-shaping dispersion layer comprised of silicone oil and microspheres and thus lacks the requisite suggestion or motivation to make the alleged combination proposed by the Office. Contrary to the Office's assertion, one of skill in the art would not have been motivated to look to the disclosure of the '812 patent for guidance in arriving at an uncured self shaping dispersion layer comprised of silicone oil and micropsheres, much less the stated layer having a particular viscosity.

Accordingly, for at least these reasons, it is respectfully submitted that the Office has failed to present a *prima facie* case of obviousness and, as such, the current rejection of Claims 29-30 must be withdrawn.

**D. U.S. Patent Number 4,701,230**

The Office has also rejected Claims 31-33 as allegedly being obvious and unpatentable over the disclosures of Wild and Snyder further in view of U.S. Patent Number 4,701,230 (hereinafter "Loi").

Once again, Claim 20, the independent claim from which Claims 31-33 depend, is non-obvious and in condition for allowance as set forth in detail above. Thus, for at least

this reason alone, the instant rejection of Claims 31-33 must also be withdrawn. However, notwithstanding this fact, the Office's further reliance on the disclosure of "Loi" is similarly misplaced.

The Office contends that it would have been obvious further in view of Loi to remove air from the self-shaping dispersion within the sealed shell. To this end, the Office has misconstrued the relevant feature of Applicants' Claims. Specifically, Applicants' recite, in part, removing air from the self-shaping dispersion prior to passing the self-shaping dispersion through the fill opening. In contrast, and as recognized by the Office, Loi only teaches removing air from the curable silicone gel material after the material has been charged into the chamber. Accordingly, even assuming *arguendo* that one of skill in the art would seek to combine the disclosure of Loi with the combined teachings of Wild in view of Snyder, which he would not, the resulting combination would for at least this reason still fail to provide the process of Applicants' Claims.

Moreover, notwithstanding the fact that the proposed combination of Wild in view of Snyder and further in view of Loi fails to teach or suggest Applicants' claims as a whole, the requisite motivation to make the proposed combination is also notably absent. Specifically, there is no teaching in Loi to remove air from a self shaping dispersion that remains uncured. Thus, one of skill in the art would not be motivated to seek guidance from Loi for the removal of air from a self shaping dispersion.

Accordingly, for at least these reasons, it is respectfully submitted that the Office has failed to present a *prima facie* case of obviousness and, as such, the current rejection of Claims 31-33 must be withdrawn.



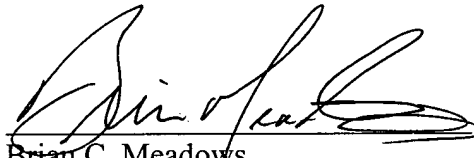
CONCLUSION

In view of the foregoing Amendments and Remarks, it is respectfully asserted that the rejections set forth in the Office Action of January 11, 2005 have been overcome and that the application is in condition for allowance. Therefore, Applicants respectfully seek notification of same.

A credit card payment authorization form, authorizing payment in the amount of \$450.00, is enclosed for the requisite Two-Month Extension of Time fee. No additional fee is believed due; however, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: MAIL STOP FEE AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.



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Date